UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,377	02/12/2001	Andre Rosenthal	147-211P	7286

2292 7590 10/29/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.**	**Applicant(s)**	
	09/647,377	ROSENTHAL ET AL.	
	Examin r	**Art Unit**	
	Scott D. Priebe	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): the rejection of claim 40 for introducing new matter.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *none*.

   Claim(s) objected to: *none*.

   Claim(s) rejected: *1-8,12,13,20,21,23-26,29 and 36-41*.

   Claim(s) withdrawn from consideration: *9-11,14-19,22,27,28 and 30-35*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Scott D. Priebe
Primary Examiner
Art Unit: 1632

Continuation of 2. NOTE: proposed claim 7 is an improper multiple dependent claim, claim 5 is also multiple dependent. Also, claims 5 and 6 are directed to vectors, not isolated nucleic acid molecules. Consequently, the subject matter of claim 7 goes beyond that of claims 5 or 6, as claim 7 is not limited to transforming with vectors .

Continuation of 5. does NOT place the application in condition for allowance because: With respect to the drawings, Applicant indicates that copies of the papers filed 4/21/03 had been provided. However, no such copies were received by the PTO. Upon further review of the papers filed 4/28/03, the petition is present, and would have been granted had the petition been accompanied by three (3) sets of the color drawings. Only one set was received. With respect to the description of Fig. 2, the description was amended on 3/10/03, and does not recite any SEQ ID NOs whatsoever. The inclusion of the additional sequences in the Sequence Listing by the amendment filed 8/27/01 is acknowledged. With respect to utility, Applicant alleges that the claimed nucleic acid molecules can be used to make a non-human transgenic animal, and that such a transgenic animal is a "real world" use. In order for a product to meet the utility requirement by its use in making another product, the product made must also meet the utility requirement. The instant specification teaches making transgenic animals (para. bridging pages 14-15), but asserts no use for such animals. Using the animal merely to see what results from incorporation of the claimed nucleic acid molecule is not a "real world" use. It is simply using the claimed invention as an object of further research. In re Kirk, 153 USPQ 48 (CCPA 1967); Brenner v. Manson, 148 USPQ 689 (US 1966). With respect to Example 7, the specification suggests that human LOBO may be a candidate gene for AHO. There is no evidence of record confirming this suggestion. The example postulates that loss of function for a gene at 2q37, possibly LOBO, may be responsible for an AHO phenotype. Whether or not human patients would benefit from modulation of LOBO expression is not at issue here. Since AHO has an essentially opposite phenotype from that observed for mice lacking LOBO function, if in fact loss of LOBO in humans confers AHO, it is likely that nucleic acid encoding human LOBO does not meet the requirements of the claimed invention. AHO is not characterized by bone elongation, which the claimed invention requires for loss of function. Finally, Applicant again asserts that the invention might be used to treat other diseases, such as achondrodysplasia. The specification does not contain such an assertion, and whether one of skill in the art may speculate on the potential use of the claimed invention to treat this disease is not relevant to whether the instant specification meets the utility requirement. With respect to possession of a genus of nucleic acid molecules, Applicant points to a variety of evidence that the human LOBO and mouse LOBO genes are orthologues, and then makes a leap of logic and concludes they are functional homologues as well. However, the only evidence of record as to the function of the human and mouse LOBO genes suggests they are not functional homologues. The specification (last sentence) shows that Applicant had recognized that even though genes are orthologous, they may have different functions. Again, there is no evidence of record that the human LOBO nucleic acids even meet the limitations of the claims, that loss of function (in humans) results in bone elongation. With respect to the rejections under 102 and 112, 2nd para., the proposed amendment has not been entered and the arguments are moot.